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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191

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EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

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DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,242

Applicant(s)

HASELBECK ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,31,45-69 and 71-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,31,45-69 and 71-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5, etc.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to the Election filed June 30, 2003, in Paper No. 18.

New claims 101 and 102 are acknowledged. Claims 1-102 are pending in the instant application.

Claims 1-11, 13-30, 32-44 and 70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 18.

Claims 12, 31, 45-69 and 71-102 have been examined on the merits.

Election/Restrictions

Applicant's election with traverse of Group IV (claims 12 and 31), SEQ ID NO:1463 as the *yphC* antisense, SEQ ID NO:4228 as the *yphC* sense nucleic acid, SEQ ID NO:12600 as the YphC polypeptide, and *Staphylococcus aureus* as the organism, in Paper No. 18 is acknowledged. The traversal is two-fold. First Applicants argue that the *yphC* nucleic acids and YphC polypeptides should be examined in a single patent application. Applicants argue that the *yphC* nucleic acids and YphC polypeptides share sufficient structural and biological relationship to permit examination of each of these claimed sequences in a single application. This is not found persuasive because as argued in the previous Restriction Requirement, filed August 22, 2003, the completely separate chemical types of the inventions regarding the *yphC* nucleic acids and YphC polypeptides supports the undue search burden if both were examined together.

Applicants also argue that the *yphC* antisense nucleic acids claimed in the instant invention contain regions of substantial overlap with each other and have substantial sequence

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identity. This is not found persuasive because as argued in the previous Restriction Requirement, filed August 3, 2003, the instant antisense nucleic acid sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct because each sequence has a unique nucleotide sequence, each nucleic acid sequence targets a different and specific region of the *yphC* gene, and each antisense nucleic acid, upon binding to the *yphC* gene, functionally modulates the expression of the gene. Furthermore, a search of more than one of the *yphC* antisense sequences presents an undue burden on the Patent and Trademark Office due to the complex nature of the search.

Secondly, Applicants argue the Election of Species for claims 48, 50, 88 and 90. It is noted that claims 48, 50, 88 and 90 have been amended rendering this Election of Species moot. However, Applicant has added new claims 101 and 102, which recite several dozen microorganisms. Claims 101 and 102 links claims 48 and 88. The Examiner agrees that the restriction between the linked inventions is subject to the nonallowance of the linking claims 101 and 102.

Upon the allowance of the linking claim(s), the restriction as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a

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restriction is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The Information Disclosure Statements, filed May 10, 2002, August 10, 2002, October 7, 2002, October 25, 2002, March 24, 2003, April 14, 2003, and July 31, 2003 are acknowledged. The references cited therein have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 and 85 recites the limitation "said determining step" in line 1. There is insufficient antecedent basis for this limitation in the claim because the claims from which claims 45 and 85 depend reference "determining the degree" not "determining step".

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 31, 45-69 and 71-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is for Written Description.

The claims are drawn to a method for screening a candidate compound for the ability to reduce cellular proliferation comprising the administration of an antisense nucleic acid complementary to a portion of a nucleic acid encoding a gene product in a cell to reduce the activity of the gene product, thereby producing a sensitized cell, wherein the gene product whose activity is reduced by an antisense comprising SEQ ID NO:1463.

The claimed invention encompasses any gene product in a cell whose activity is reduced by an antisense comprises SEQ ID NO:1463. The Specification as filed only provides a description of the *Staphylococcus aerues* gene, whose activity is reduced by an antisense comprising SEQ ID NO:1463. The Specification at age 127, Example 4, describes that "since bacterial genes are transcribed in a polycistronic manner, the antisense inhibition of a single gene in an operon might affect the expression of all the other genes on the operon or the genes downstream from the single gene identified". The Specification as filed contemplates other bacterial genes, where only the *Staphylococcus aerues* gene is described.

The specification fails to describe the complete structure of a representative number of species of the claimed genus. See the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement (Vol. 66, No. 4, pages 1099-1111). These guidelines state that: "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention." In the instant case, the specification does not describe or identify characteristics that can be used to distinguish species of the claimed genus.

Additionally, "[T]he skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims

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directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence."


Applicant's specification does not provide a sufficient number of gene products in a cell whose activity is reduced by an antisense comprising SEQ ID NO:1463, which would allow one of skill in the art to predict the structures of all members of the claimed genus of gene products. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Therefore, the specification does not describe the claimed compounds in such full and concise terms so as to indicate that the applicant had possession of these compounds at the time of filing of this application. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
September 17, 2003


KAREN A. LACOURCIERE, PH.D.
PRIMARY EXAMINER